REMARKS/ARGUMENTS

Applicants thank the Examiner for the considered response and explicit prior art references. Claims 1 and 4 have been amended. Claims 1 - 6 stand rejected and remain in the case. Reconsideration of the patent application is respectfully requested in view of the foregoing amendments and following remarks

The instant invention is drawn to a suture, graft or suture/graft combination having a polymer coating containing releasable biological agents for the prevention and reduction of smooth muscle cell proliferation in a sutured, grafted or injured area of a vessel or arterial wall.

Claim 1 as amended recites "A suture, graft or suture/graft combination comprising PTFE and having a polymer coating containing releasable biological agents for the prevention and reduction of intimal hyperplasia, smooth muscle cell proliferation in a sutured, grafted, or injured area of a vessel or arterial wall." Amended claim 4 calls for "A suture, graft or suture/graft combination comprising PTFE having a reservoir containing releasable biological agents for the prevention and reduction of intimal hyperplasia, smooth muscle cell proliferation in a sutured, grafted area or injured area of a vessel or arterial wall, said biological agent being osmotically released through the pores in the reservoir."

The amended claims also recite the reduction and prevention of intimal hyperplasia. None of the cited references teaches this feature of the instant invention. Applicants have observed long-term restenosis and intimal hyperplasia in surgical patients and attribute it to the inefficient delivery of the coated drugs. The adhesion of the drugs to and delivery from smooth-walled surfaces of devices is thought to be erratic and inefficient over long periods, although short term effects may be similar in preventing SMC etc.

Claims 1 and 2 have been rejected under 35 U.S.C. §102(b) as being anticipated by Shibuya (USPGPUB 2002/0055759, "Shibuya").

Shibuya discloses a surgical suture coated with one or more biologically active compounds. Shibuya also discloses a method of making a coated suture, placing the coated suture in an organism, and a method of using the coated suture in the treatment of diseases, such as cancer. Biologically active compounds that may be used include antibiotics, antifungal, anti-viral, anti-microbial compounds and the like (col. 5, paragraph 0038).

Although the Examiner states that the limitation "plasma-assisted coating," recited in instant claim 2, is inherent in the teachings of Shibuya, since Shibuya teaches surgical suture coating used to deliver one or more biologically active compounds, the amended claims more truly reflect the instant invention.

The Shibuya reference, the Examiner implicitly asserts, teaches each and every element of claims 1 and 2 as required for anticipation under 35 U.S.C. §102(b). It is shown that the reference is directed to an entirely different process in the art. The Shibuya reference teaches a method of coating "a biologically active compound on a suture" (p. 2, paragraph 0013). Shibuya does not teach the instant suture material, PTFE, recited in the amended independent claims 1 and 4. Shibuya has no reference whatsoever to grafts or suture/graft combinations recited in instant claims 1 and 2. Shibuya does not teach plasma coating the suture with a polymer as recited in claim 2. In fact Shibuya coats Interleukins and the like directly on the suture material from solution -- with no plasma coated polymer. While the biological compounds of Shibuya are alleged to be curative, they do not prophylactically prevent smooth muscle cell proliferation as recited in the instant claims. Shibuya does not address reduction and prevention of intimal hyperplasia, the mechanism of which, as argued above, is different from administering drugs to cancer cells cited in Shibuya's examples. For these reasons, Applicants respectfully request the withdrawal of the rejection under Shibuya, since it does not teach most of the elements of the instant claims 1 and 2.

Narayanan discloses coated medical devices and a process for coating medical devices used to treat a particular condition. The method comprises the steps of preparing an aqueous latex polymeric emulsion, adding at least one drug, agent and/or compound, in therapeutic dosages, to the aqueous latex polymeric emulsion for the treatment of a predetermined condition (col. 2, lines 56 - 62).

Claims 1 - 3 stand rejected under 35 U.S.C. §102(e) as being anticipated by USP 6,919,100 ("Narayanan").

The rejection of claims 1 - 3 in view of Narayanan is traversed on the grounds that Narayanan does not teach each and every element of the instant amended claims. The cited reference does not teach PTFE sutures, grafts or suture/graft combinations. The Examiner admits that Narayanan teaches in col. 2, lines 56 - 62 coating a medical device with an aqueous latex polymer solution containing a drug, agent or compound, but proceeds to assert that plasma-assisted coating of a polymer is inherent in the teachings (instant office action; p. 4, last paragraph). The Examiner's arguments are respectfully believed to be inconsistent.

Narayanan in fact teaches away from the polymer coating method. Applicants agree that Narayanan teaches coating rapamycin and the like on a suture or a graft to prevent SMC hyperplasia. However the instant invention is directed to a PTFE suture, graft or suture/graft combination coated with a polymer that holds the drug. The porosity of the PTFE provides additional benefits that other suture materials do not. The porosity allows the coated material (the plasma-assisted coated polymer, for instance) better adhesion to the device. Smooth sutures or grafts, on the other hand, would have a loosely adhered coating of polymers and drug and elution would not be as controlled or predictable. Further, the inhibition of intimal hyperplasia differs in mechanism from SMC hyperplasia, restenosis and vascular occlusion, as argued above. It is not clear to Applicants that the device structure/drug combination of Narayanan would be equally effective in inhibiting or reducing intimal hyperplasia. Applicants respectfully request withdrawal of the rejection based on Narayanan for the above reasons.

Claims 1 - 6 stand rejected under 35 U.S.C. §102(e) as being anticipated by USP 6,890,546 to Mollison et al. ("Mollison"). Claims 1 - 6 are also rejected under 35 U.S.C. §103 as being obvious over Mollison.

The Examiner has argued that Mollison teaches each and every element of the claims 1 - 6 as required for anticipation under 35 U.S.C. § 102(e). He then proceeds to reject the same claims under 35 U.S.C. 103(a) arguing that there are elements of the instant claims that are not taught but would be prima facie obvious to one of ordinary skill in the art. This is inconsistent. The Examiner does not state which elements of the claims are not taught by Mollison. Further, it is not clear why it would be obvious to one of ordinary skill in the art or why Mollison would be motivated to coat PTFE sutures, grafts or suture/graft combination as claimed by the Applicants.

Mollison does not teach each and every element of the instant claims. It does not teach a PTFE suture or graft or suture/graft combination of the instant claims 1 and 4. In fact Mollison does not teach coated sutures at all. Mollison uses polymer coated devices, but does not teach coating a PTFE device with a polymer as recited in claim 2. The assertion that plasma-assisted coatings is inherent is not supported by any scientific arguments. Polymer coatings may be applied by numerous methods, including from aqueous solutions as shown above. Thus, Mollison's polymer coated device may be coated by any one of several available means. Plasma coating is not inherent or implicit in the teachings. Mollison lists (col. 12, lines 9 - 57) polymeric materials that may be used to coat the medical devices. But the class of fluoro-alkenes (PTFE) is notably absent from the list.

The Examiner stated that Mollison teaches a polymer coated device that may be impregnated with a rapamycin analog to prevent SMC proliferation, inhibit neointimal hyperplasia and the like. However, Mollison does not discuss long-term intimal hyperplasia and restenosis which Applicants' porous suture-drug combination seeks to prevent. Applicants request the withdrawal of the rejections in view of the arguments presented. Porous PTFE may be used as a medical device carrying the drug (claims 4 - 6) or it may be plasma-coated with another porous polymer that carries the drug (claims 1 - 3).

While PTFE suture materials, polymer coated medical devices and (rapamycin) drug-eluting devices are individually known, the instant combination is novel and unobvious, and provides benefits not seen from the material/drug combinations listed in the instant references.

The cited references do not teach the use of PTFE sutures or grafts. Although PTFE is a widely used material in surgery, especially sutures, its inventive use for coating with a drug-eluting polymer, as now recited in the claims, would not be obvious to one of ordinary skill in the art. The invention exploits the toughness of PTFE sutures and grafts with the added adhesion provided to the coated polymer by the porosity of the PTFE base. Where the drugs are delivered from a reservoir, the porous PTFE suture provides a superior osmotic delivery than smooth-walled sutures.

For these reasons Applicants request the withdrawal of all rejections allowance of claims 1 - 6, and passing the application to allowance.

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